IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION
No. 7:22-CV-73-M

CENTER FOR ENVIRONMENTAL HEALTH, ET AL., PLAINTIFFS v. MICHAEL S. REGAN, ADMINISTRATOR OF THE U.S. ENVIRONMENTAL PROTECTION AGENCY, AND THE U.S. ENVIRONMENTAL PROTECTION AGENCY, DEFENDANTS	**PLAINTIFFS' SUPPLEMENTAL MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS**

Plaintiffs submit this Supplemental Memorandum to address the three questions in the Court's January 23, 2023 Order. Before turning to these questions, we underscore why this case is vitally important to citizens of the Cape Fear basin.

Because of 40 years of pollution by the Chemours plant in Fayetteville, the downstream stretch of the Cape Fear River was and is contaminated by hundreds of Per- and Polyfluoroalkyl Substances ("PFAS"), poisoning drinking water consumed by over 500,000 people. Chemours conducted no health effects testing on nearly all of these PFAS, leaving communities unable to determine how PFAS exposure impaired their health. As a result, plaintiffs petitioned the Environmental Protection Agency ("EPA") to use its broad authority under the Toxic Substances Control Act ("TSCA") to require Chemours to fund extensive testing of 54 PFAS. EPA asserted

it was "granting" the petition but in fact rejected the comprehensive research program developed by plaintiffs' scientific experts and claimed that limited testing on a small number of PFAS under its PFAS Testing Strategy would provide the answers that communities need.

EPA is now asking the Court to unconditionally defer to its misleading characterization of its petition response and dismiss this case. If granted, dismissal would leave a population heavily stressed by long-term pollution without a judicial remedy for an EPA decision that fails to protect their health and allow the company that has contaminated their blood, air, soil, food supply, and drinking water to escape accountability for testing.

I. What Constitutes a Petition under the Toxic Substances Control Act (TSCA)?

Section 21 of TSCA has been described as an "unusually powerful procedure[] for citizens to force EPA's hand. " *Trumpeter Swan Society v EPA*, 774 F.3d 1037, 1939 (D.C. Cir. 2014). TSCA's legislative history underscores that "[t]he responsiveness of government is a critical concern and the citizens' petition provision will help to protect against lax administration of the [TSCA]." S. Rep. 94–698, reproduced at 1976 U.S.C.C.A.N. 4491, 4503. As emphasized in *Food & Water Watch, Inc. v. EPA,* 302 F. Supp. 3d 1058, 1066 (N.D. Cal. 2018), "the role of citizen oversight, including access to federal courts, weighs considerably" under section 21.

Section 21(a) authorizes "any person" to petition EPA for issuance of a rule or order under TSCA section 4, which empowers EPA to compel companies to conduct health or environmental effects testing on their chemicals. Under section 21(b)(1), the petition "shall set forth the facts which it is claimed establish that is necessary" to take the action requested. Within 90 days, EPA must grant or deny the petition. The reasons for a denial must be published in the Federal Register and the petitioner may file suit to "compel the Administrator to initiate a rulemaking proceeding as requested in the petition." In these suits, section 21(b)(4)(B) affords the petitioner "the

opportunity to have such petition considered by the court in a *de novo* proceeding." Section 21(b)(4)(B)(i) specifies the findings required to justify testing requirements and, if the "preponderance of the evidence" supports these findings, the court has no discretion but to "order the Administrator to initiate the action requested by the petitioner." By contrast, no judicial remedy is available where EPA "grants" a petition, likely because Congress presumed that since the Agency has agreed to take the actions requested by the petition, judicial intervention is unnecessary.

In this case, plaintiffs' October 2020 petition asked EPA to issue TSCA testing orders to Chemours to develop data enabling Cape Fear communities to understand how their health has been affected by long-term exposure to PFAS produced by the company. Exh. 1 to Def. Motion to Dismiss (ECF 49). The petition targets 54 Chemours-manufactured PFAS to which residents have likely been exposed through their blood, air, soil, food supply, and drinking water. Given the paucity of data on these PFAS, the petition presents a detailed testing program, developed by plaintiffs' scientific advisors, to determine their effects on health and the environment. This program includes, *inter alia*, long-term studies in laboratory animals to assess whether certain PFAS cause cancer, reproductive damage, liver toxicity and other serious diseases; testing of PFAS mixtures found in drinking water to assess the impact of real-world exposure to multiple PFAS simultaneously; and an epidemiological study of the Cape Fear population to examine the relationship between actual human exposure and mortality and disease. Id. at 23-33.

II. What is the Relationship Between the 54 Chemicals and the PFAS Class of Chemicals under the Statute and the Caselaw?

On December 28, 2021, EPA "granted" the petition but, to plaintiffs' dismay, rejected issuing test orders for nearly all the 54 PFAS and refused to require nearly all the studies called for by the petition. Exh. 2 to Def. Motion to Dismiss (ECF 49). EPA maintained that limited

studies on 7 of the 54 PFAS under its PFAS Testing Strategy would meet the data needs identified in the petition and that several requested studies (i.e. epidemiological research and mixture testing) were unnecessary.

The question now before the Court is whether, on a motion to dismiss, it should accept EPA's claim that it "granted" plaintiffs' petition. "[C]ourts have long looked to the *contents* of the agency's action, not the agency's self-serving *label*, when deciding" whether the agency's actions are insulated from judicial review. *Azar v. Allina Health Services,* 139 S.Ct. 1804, 1812 (2019) (emphasis in original).[1] Moreover, at this threshold stage of the case, the Court must treat the allegations in the Complaint as true and construe them in the light most favorable to plaintiffs.[2]

The best gauge of whether EPA "granted" the petition is a side-by-side comparison of the testing plaintiffs proposed with the studies EPA actually agreed to require. As the Amended Complaint demonstrates, the testing to which EPA committed is a small subset of the comprehensive research program outlined in the petition. For example, the petition response:

- Failed to require testing on 47 of the 54 PFAS;
- Conditioned testing for 7 PFAS on a "tiered" approach that could result in no animal studies for the critical end-points highlighted in the petition;
- Did not address the petition's request for multigeneration or extended one-generation and 2-year rodent carcinogenicity studies on the 14 Tier 1 PFAS with substantial exposure from drinking water and/or presence in human blood;
- Did not require testing for GenX compounds despite the recognition in EPA's own toxicity assessment of major data-gaps for these ubiquitous and harmful PFAS;

[1] See also decisions cited on pp. 12-13 of Pl. Opp. to Def. Motion (ECF 52)

[2] Dismissal is not warranted "unless it appears to a certainty that the plaintiff would be entitled to no relief under any state of facts which could be proved in support of his claim." *Johnson v. Mueller,* 415 F.2d 354, 355 (4th Cir. 1969). Where the claimed basis for dismissal is "that a complaint simply fails to allege facts upon which subject matter jurisdiction can be based," the "facts alleged in the complaint are taken as true, and the motion must be denied if the complaint alleges sufficient facts to invoke subject matter jurisdiction*." Kerns v. U.S.*, 585 F.3d 187, 192 (4th Cir. 2009). As the Fourth Circuit held in *Adams v. Bain,* 697 F.2d 1213, 1219 (4th Cir. 1982), "where the jurisdictional facts are intertwined with the facts central to the merits of the dispute," the "entire factual dispute is appropriately resolved only by a proceeding on the merits."

- Refused to require a comprehensive epidemiological study of North Carolina residents exposed to the PFAS pollution created by the Chemours facility;
- Rejected requiring biomonitoring of Chemours employees;
- Declined to require testing on PFAS mixtures found in the drinking water and/or blood of Cape Fear residents;
- Refused to require Chemours to develop and submit analytical standards and methods on the 54 PFAS; and
- Failed to address the petition's requests for ecotoxicity and fate and transport studies on the 54 PFAS.

Am. Com. (ECF 32) ¶¶ 82-110. This comparison starkly demonstrates the disconnect between the petition and EPA's response, a gap that is further revealed by EPA's explanation for limiting the scope of testing. Based on its PFAS Testing Strategy, EPA claimed that studying a few "representative" chemicals out of the 6500+ members of the PFAS class would provide Cape Fear residents a meaningful understanding of the health impacts of the specific PFAS in their blood, air, soil, food and drinking water. But, as the Amended Complaint explains, this logic rests on the dubious assumption that the Agency "could make judgments about [the 54 PFAS'] health impacts on Cape Fear communities by 'extrapolating' from data on other substances." According to the Amended Complaint, this is a "highly theoretical and unproven approach, based on complex computational models that have not been peer reviewed." Id. ¶ 87. Thus, as 50 leading scientists emphasized in a December 20, 2021 letter to EPA, "[t]he testing strategy will have limited value in informing exposed communities about the health impacts of PFAS pollution because the 24 test substances were selected without regard to whether they are widespread in the environment and human blood and contribute significantly to exposure and risk." Id. On a motion to dismiss, the Court must accept these statements as true and correct.

EPA has authority under TSCA section 26(c)(2)(A) to take action under section 4 and other

provisions "with respect to a category of chemical substances or mixtures." However, whether a group of substances is "suitable for classification as [a category] for purposes of this chapter" is a fact-based case-by-case judgment.[3] EPA has used categories sparingly under TSCA and there is no precedent for issuing section 4 testing orders on a small number of substances to determine how a much larger universe of substances has impacted the health of an exposed community.

Thus, on a motion to dismiss, the Court cannot accept on faith EPA's assertion that testing on "representatives" of the PFAS category will meaningfully illuminate the health impacts of the specific PFAS to which Cape Fear communities have been exposed. Instead, this disputed issue, along with the overall merits of plaintiffs' petition, must be resolved in a *de novo* proceeding under section 21(b)(4)(B) of TSCA. In that proceeding, plaintiffs would present expert testimony that, while the Testing Strategy may have other benefits, it cannot eliminate the need for conducting studies on the 54 PFAS specified in the petition. If plaintiffs are able to "demonstrate to the satisfaction of the Court by the preponderance of the evidence" that testing these 54 PFAS is justified under TSCA, the Court would need to order EPA to grant the relief sought by the petition.

Allowing EPA to avoid a *de novo* proceeding by the slight-of-hand maneuver of claiming that it "granted" a petition would negate the unusually broad responsibility of district courts to independently determine the merits of section 21 petitions. Having concluded that nearly all the testing requested by plaintiffs was unnecessary, the obvious course was for EPA to "deny" their petition, as it has done for numerous other petitions that it chose to reject,[4] and defend the merits of its decision before the Court. Here, however, EPA has sought the best of both possible worlds:

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[3] Plaintiffs agree that a category approach may be useful in regulating PFAS-containing products, drinking water contamination or surface water discharges. However, where the goal of testing is to help communities understand the health impacts of PFAS exposure, limiting testing to a few "representative" substances is unlikely to delineate community-specific patterns of mortality and disease.

[4] Since September 2007, EPA has denied or partially denied twenty-eight section 21 petitions and granted only 2 (not including the petition at issue here).

to reject the testing requested in the petition and (by calling its decision a "grant") to avoid a legal challenge. The Court should not countenance this tactic. "[A]gencies may not use shell games to elude review." *Tesoro Alaska Petroleum Co*. v. FERC, 234 F.3d 1286, 1293 (D.C. Cir. 2000).

III. What Level of Deference is Appropriate to EPA's Determination of What Appropriate Proceedings-Processes And Procedures it Intends to Implement for Testing the Chemical(s) under the TSCA?

If EPA "grants" a petition for testing, section 21(b)(2) provides that it must "commence an appropriate proceeding" under section 4. However, a determination that EPA in fact "denied" the petition (the only conclusion now warranted given the allegations in plaintiffs' Amended Complaint) requires a different path: the Court must examine the validity of the petition in a *de novo* proceeding. By its nature, such a proceeding precludes deference to the administrative steps EPA is taking to implement its petition response. Instead, the only focus of the Court is whether the "predominance of the evidence" presented meets the testing criteria in section 21(b)(4)(B)(i):

> "(I) information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance to be subject to such rule or order; and (II) in the absence of such information, the substance may present an unreasonable risk to health or the environment . . . "

If it makes these findings,[5] TSCA commands the Court to "order the Administrator to initiate the action requested by the petitioner." EPA would thus need to implement the testing program proposed in the petition, not the far smaller program called for by its petition response.

Based on earlier briefing, the Court may be under the impression that the only issue subject to judicial consideration under section 21 is the selection of substances to undergo testing and that EPA must receive broad deference in choosing the "methodologies and protocols" to be employed. Def. Mot. at 2, 16. This is incorrect. Under sections 4(a)-(b), test orders must specify the health

[5] EPA's petition response does not dispute these findings and the bar for meeting them is very low. *Chemical Manufacturers Association v. U.S. Environmental Protection Agency,* 859 F.2d 977, 984-987 (1988).

and environmental effects to be investigated and the studies to be conducted.[6] Section 4(b)(2)(A) provides a detailed menu of effects and study types that orders may incorporate. Within this broad universe, plaintiffs' petition identifies the health effects (e.g. cancer, reproductive harm and liver toxicity) of greatest concern for exposed Cape Fear populations and the testing strategies (e.g. cancer bio-assays, mixture testing and epidemiology studies) most likely to develop useful data for diagnosis and treatment of residents' medical conditions. Exh. 1 to Def. Mot. at 23-33. In the *de novo* proceeding required under section 21(b)(4)(B), the Court would need to independently examine the evidence justifying these elements of the petition, with no deference to EPA. For example, EPA's petition response rejects a human epidemiological study, which plaintiffs consider absolutely critical because of the value of analyzing the relationship between PFAS exposure and mortality and disease in the Cape Fear population. Am. Com. ¶¶ 97-103. EPA's reasons for rejecting this study would be considered along with other evidence in the *de novo* proceeding but would not receive special weight.

EPA has previously maintained that implementation of the PFAS Testing Strategy represents a "proceeding" that effectively addresses the goals of plaintiffs' petition. Def. Mot. at 15-19. However, the Strategy is progressing at a snail's pace. EPA initially promised to issue 24 PFAS testing orders under the Strategy by the end of 2021. But only two orders have been issued over a year later. Def. Mot. at 8-9; Def. Notice of TSCA Section 4 Test Order (ECF 65). EPA has no timetable for issuing testing orders for the 22 other "representative" substances. Moreover, the initial scope of testing under the two orders is extremely limited and includes none of the major

[6] EPA suggests that its only disagreement with plaintiffs is on the selection of "protocols and methodologies," an area where it claims broad discretion. Def. Mot. at 16-18. However, as used in TSCA and EPA regulations, these terms refer to the details of *how* testing is conducted, not the types of studies to be performed or the substances to be tested, which are the principal focus of the proposed testing program in plaintiffs' petition. Protocols (or study plans) are typically developed by the manufacturer *after* a test rule or order is in place prescribing the basic parameters of testing.

health effects studies called for by the petition. These studies could be required under a second tier of testing but there is no guarantee of this and any further testing is far off. And while EPA has made vague references to ongoing analyses that could lead to additional testing of the 54 PFAS (Def. Mot. at 9-10), there is no realistic expectation of such testing any time soon. Thus, at best, the process that EPA describes as an "appropriate proceeding" under section 4 is merely a promise to consider future testing. See Pl. Opp. to Def. Motion at 24-26.

Conclusion

EPA's motion to dismiss should be denied.

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Respectfully submitted,

/s/ Robert M. Sussman
ROBERT M. SUSSMAN
Sussman & Associates
3101 Garfield Street, NW
Washington, DC 20008
(202) 716-0118
District of Columbia Bar No. 226746
bobsussman1@comcast.net

Attorney for Plaintiff

/s/ Thomas J. Lamb
Thomas J. Lamb
Law Offices of Thomas J. Lamb, P.A.
1908 Eastwood Rd., Ste. 225
Wilmington, NC 28403
TJL@LambLawOffice.com
(910) 256-2971
Fax (910) 256-2972
State Bar No. 18787

Local Civil Rule 83.l(d) Counsel for Plaintiffs

MICHAEL CONNETT
CA Bar No. 300314

Waters, Kraus and Paul
222 North Pacific Coast Highway
Suite 1900
El Segundo, California 90245
mconnett@waterskraus.com
(310) 414-8146

Attorney for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of February 2023, a true and correct copy of the foregoing Supplemental Memorandum was filed electronically with the Clerk of the Court using CM/ECF. I also certify that the foregoing is being served on all counsel of record via Notice of Electronic Filing generated by CM/ECF.

/s/*Robert M. Sussman*
ROBERT M. SUSSMAN
Sussman & Associates
3101 Garfield Street, NW
Washington, DC 20008
(202) 716-0118
District of Columbia Bar No. 226746
bobsussman1@comcast.net

Attorney for Plaintiffs